UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF MICHIGAN
SOUTHERN DIVISION

CLINTON THORN,

Plaintiff,

v.

MEDTRONIC SOFAMOR DANEK, USA, INC., and MEDTRONIC, INC.,

Defendants.

_____/

Case No. 1:13-cv-239

HON. JANET T. NEFF

OPINION

Pending before the Court in this diversity-products liability action is Defendants' Motion to Dismiss (Dkt 50). Plaintiff filed a response in opposition to Defendants' motion (Dkt 52), and Defendants filed a reply (Dkt 53). Defendants have also since filed numerous supplemental authorities for the Court's consideration (Dkts 54-57, 61-62). Having conducted a Pre-Motion Conference in this matter and having fully considered the parties' written briefs and accompanying exhibits, the Court finds that the relevant facts and arguments are adequately presented in these materials and that oral argument would not aid the decisional process. *See* W.D. Mich. LCivR 7.2(d). For the reasons that follow, the Court determines that Defendants' motion is properly granted.

I. BACKGROUND

Defendants designed and manufactured the medical device at issue in this case: "Infuse," a bio-engineered bone filling material containing a bone morphogenetic protein (Dkt 35, Amend.

Compl. ¶ 7).[1] Infuse is used as an alternative in certain spinal surgeries to graft a patient's own bone (*id.*). The purpose of Infuse is to accomplish the same clinical outcomes as grafting a patient's own bone, without the pain often associated with grafting bone from the hip or other sites (*id.*).

The Food and Drug Administration (FDA) approved Infuse on July 2, 2002 for use in the lower, lumbar region of the spine to treat degenerative disc disease (Dkt 35, Amend. Compl. ¶ 10). It was approved by the FDA for anterior-approach lumbar surgery (performed through the abdomen) surgeries at L4 though S1 in combination with an "LT-Cage" and a spongy carrier or scaffold (*id.*). Infuse's FDA-approved label indicates the following:

> The InFUSE™ Bone Graft/LT-CAGE™ Lumbar Tapered Fusion Device consists of two components containing three parts—a tapered metallic spinal fusion cage, a recombinant human bone morphogenetic protein and a carrier/scaffold for the bone morphogenetic protein and resulting bone. The InFUSE™ Bone Graft is inserted into the LT-CAGE™ Lumbar Tapered Fusion Device component to form the complete InFUSE™ Bone Graft/LT-CAGE™ Lumbar Tapered Fusion Device. **These components must be used as a system. The InFUSE™ Bone Graft component must not be used without the LT-CAGE™ Lumbar Tapered Fusion Device component.**

(Defs.' Ex. 3, Dkt 51-3 at 2) (emphases in original). The label further indicates that the device "is to be implanted via an anterior . . . approach," warning that "[t]he safety and effectiveness of the InFUSE Bone Graft component . . . used in surgical techniques other than anterior . . . approaches have not been established" (*id.* at 4-5). The label expressly cautions that "the potential for ectopic . . . or undesirable exuberant bone formation exists" (*id.* at 6).

Plaintiff, a Michigan resident, had a spinal surgery on March 4, 2010 using Defendants' Infuse device in an off-label manner, i.e., in a posterior-approach lumbar surgery (performed through

[1]This Court has another case on its docket, *Wright v. Medtronic*, No. 1:13-cv-716, involving the same device also implanted in an off-label manner.

the back) (Dkt 35, Amend. Compl. ¶ 10). Plaintiff claims that "his body produced ectopic and uncontrollable bone growth" because the Infuse "created bone grown outside of the cage in which it was to be confined and into Plaintiff's spinal column with the ultimate result that his spinal cord was compressed and he suffered intractable pain" (*id.* ¶ 14). Plaintiff alleges that Defendants failed to accurately explain the risks to his surgeon and, in fact, "actively misled him (and ultimately Plaintiff) by their off-label promotion of Infuse, including their financial sponsoring of physicians and articles determined to portray Infuse as safe even for off-label use" (*id.* ¶ 16). Plaintiff underwent a revised interbody fusion in April 2012, which was performed by using a piece of Plaintiff's hip bone as the grafting material in lieu of Infuse (*id.* ¶ 34). Plaintiff alleges that despite the revision surgery, he continues to suffer from significant pain and disability as a result of his exposure to Infuse (*id.* ¶ 35).

In his three-count Amended Complaint filed on October 25, 2013, Plaintiff alleges "Failure to Warn" (Count I); "Negligence and Gross Negligence" (Count II); and "Breach of Warranty" (Count III) (Dkt 35). In lieu of answering the Amended Complaint, Defendants filed a Pre-Motion Conference request, proposing to file a motion to dismiss Plaintiff's Amended Complaint (Dkt 36). Following a Pre-Motion Conference in December 2013, this Court issued a briefing schedule on the proposed motion (Dkt 41). The parties filed their motion papers in March 2014 (Dkts 50-53).

II. MOTION STANDARD

Defendants filed their motion to dismiss under FED. R. CIV. P. 12(b)(6), arguing, in pertinent part, that Plaintiff's claims are preempted. *See Trollinger v. Tyson Foods, Inc.*, 370 F.3d 602, 608 (6th Cir. 2004) (explaining that preemption does not normally concern the subject-matter

jurisdiction of a court to hear a claim, but "the merits of the claim itself—namely, whether it is viable and which sovereign's law will govern its resolution").

Defendants also assert under Rule 12(b)(6) that Plaintiff's claims fail on independent federal and state-law grounds. Under Rule 8(a)(2) of the Federal Rules of Civil Procedure, a complaint must contain a "short and plain statement of the claim showing that the pleader is entitled to relief." FED. R. CIV. P. 8(a)(2). A complaint will survive a motion to dismiss if the plaintiff alleges facts that "state a claim to relief that is plausible on its face" and that, if accepted as true, are sufficient to "raise a right to relief above the speculative level." *Bell Atlantic Corp. v. Twombly*, 550 U.S. 544, 545 (2007). The plausibility standard "is not akin to a 'probability requirement,' but it asks for more than a sheer possibility that a defendant has acted unlawfully. Where a complaint pleads facts that are 'merely consistent with' a defendant's liability, it 'stops short of the line between possibility and plausibility . . . .'" *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) (quoting *Twombly*, 550 U.S. at 570).

In deciding a motion to dismiss for failure to state a claim under FED. R. CIV. P. 12(b)(6), the court must treat all well-pleaded allegations in the complaint as true and draw all reasonable inferences from those allegations in favor of the nonmoving party. *Total Benefits Planning Agency, Inc. v. Anthem Blue Cross & Blue Shield,* 552 F.3d 430, 434 (6th Cir. 2008). "[W]hen a document is referred to in the pleadings and is integral to the claims, it may be considered without converting a motion to dismiss into one for summary judgment." *Commercial Money Ctr., Inc. v. Ill. Union Ins. Co.*, 508 F.3d 327, 335-36 (6th Cir. 2007). Also, "[a] court may consider public records without converting a Rule 12(b)(6) motion into a Rule 56 motion." *Jones v. City of Cincinnati*, 521 F.3d 555, 562 (6th Cir. 2008). *See, e.g., Chapman v. Abbott Labs.*, 930 F. Supp. 2d 1321, 1323 (M.D. Fla. 2013) (taking judicial notice of the FDA-approved label and the statements contained therein

because the label "can be accurately and readily determined from sources whose accuracy cannot reasonably be questioned"); *In re Epogen & Aranesp Off-Label Mktg. & Sales Practices Litig.*, 590 F. Supp. 2d 1282, 1286 (C.D. Cal. 2008) (granting request for judicial notice of drug labels publicly available on FDA website in connection with motion to dismiss).

"[T]he tenet that a court must accept as true all of the allegations contained in a complaint is inapplicable to legal conclusions. Threadbare recitals of the elements of a cause of action, supported by mere conclusory statements, do not suffice." *Iqbal*, 556 U.S. at 678. Further, "the court need not accept as true a legal conclusion couched as a factual allegation, or an unwarranted factual inference." *Handy-Clay v. City of Memphis, Tenn.*, 695 F.3d 531, 539 (6th Cir. 2012) (citation and internal quotation marks omitted). The parties do not dispute for purposes of this motion that the substantive law of Michigan, the forum state, applies to the issues presented. *See generally Hardy v. Reynolds & Reynolds Co.*, 311 F. App'x 759, 761 (6th Cir. 2009) (discussing choice of law rules in a diversity case).

III. ANALYSIS

A. Overview of the Parties' Arguments

The federal Food, Drug, and Cosmetic Act (FDCA), 21 U.S.C. § 301 *et seq.*, has long required FDA approval for the introduction of new drugs into the market; however, the introduction of new medical devices was left largely for the states to supervise as they saw fit. *Riegel v. Medtronic, Inc.*, 552 U.S. 312, 315 (2008). With the passage of the Medical Device Amendments of 1976 (MDA), 21 U.S.C. § 360c *et seq.*, Congress swept back some state obligations and imposed a regime of detailed federal oversight of medical devices. *Id.* "The federal statutory scheme amply empowers the FDA to punish and deter fraud against the Administration, and [] this authority is used

by the Administration to achieve a somewhat delicate balance of statutory objectives." *Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341, 348 (2001) (indicating that the FDA is empowered to investigate suspected fraud, *see* 21 U.S.C. § 372; 21 C.F.R. § 5.35, and citizens may report wrongdoing and petition the agency to take action, § 10.30).

"Off-label" usage of medical devices (use of a device for some other purpose than that for which it has been approved by the FDA) is "an accepted and necessary corollary of the FDA's mission to regulate in this area without directly interfering with the practice of medicine." *Buckman*, 531 U.S. at 350. The FDCA expressly states in part that "[n]othing in this chapter shall be construed to limit or interfere with the authority of a health care practitioner to prescribe or administer any legally marketed device to a patient for any condition or disease within a legitimate health care practitioner-patient relationship." 21 U.S.C. § 396. Thus, "the FDA is charged with the difficult task of regulating the marketing and distribution of medical devices without intruding upon decisions statutorily committed to the discretion of health care professionals." *Buckman*, 531 U.S. at 350. Defendants argue that Plaintiff's state-law claims against them encroach upon the federal enforcement scheme and are preempted by the MDA, either expressly or impliedly. Defendants further argue that Plaintiff's claims fail on several independent federal and state-law grounds.

1. *Express Preemption*

Congress included an express pre-emption provision in the MDA, which provides in pertinent part that "no State or political subdivision of a State may establish or continue in effect with respect to a device intended for human use any requirement—(1) which is different from, or in addition to, any requirement applicable under this chapter to the device, (2) which relates to the

safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under this chapter." 21 U.S.C. § 360k(a).

The United States Supreme Court set forth a two-step analysis for courts to determine whether the MDA expressly preempts a state-law claim within the meaning of § 360k(a). First, a court must determine whether the FDA has established requirements applicable to the particular medical device at issue. *Riegel*, 552 U.S. at 321. If the first step is answered in the affirmative, then the court must proceed to the second step. The second step requires a court to determine whether the state law claims are based on state requirements that are "different from, or in addition to," the federal requirements. *Id.* at 321-22. "State requirements" include a state's common law legal duties. *Id.* at 324-25. If the state requirements stemming from the claim differ from, or add to, the federal requirements, then the state claim is expressly preempted by operation of § 360k(a).

However, state claims that are premised on a violation of FDA regulations escape express preemption, as they are considered "parallel," rather than different from, or in addition to, the federal requirements. *Riegel*, 552 U.S. at 324-25. *See generally Dunbar v. Medtronic, Inc.*, No. CV 14-01529-RGK AJWX, 2014 WL 3056026, at *2 (C.D. Cal. June 25, 2014) (discussing two-step analysis). "The plaintiff must be suing for conduct that *violates* the FDCA (or else his claim is expressly preempted by § 360k(a)), but the plaintiff must not be suing *because* the conduct violates the FDCA (such a claim would be impliedly preempted under *Buckman*)." *Perez v. Nidek Co., Ltd.*, 711 F.3d 1109, 1120 (9th Cir. 2013) (emphases in original).

Defendants argue that Plaintiff's claims are expressly preempted in their entirety by the MDA, as interpreted by the Supreme Court in *Riegel*, because the claims seek to impose state-law requirements on the design, manufacture or labeling of the medical device at issue in this case that

are different from or in addition to the federal requirements imposed by the FDA (Dkt 51 at 17-21). In response, Plaintiff does not dispute that the FDA controls approval of medical devices (Dkt 52 at 6). Plaintiff rejects, however, the notion that once the FDA approves the device, the manufacturer "essentially has complete immunity from any liability (apparently regardless of whatever they do)" (*id.* at 6, 10). Plaintiff also asserts that he has stated a parallel state claim under Michigan's products liability statute, MICH. COMP. LAWS § 600.2945 (*id.* at 17-19). Plaintiff emphasizes that "it is Medtronic's knowledge of the consequences of off-label use, combined with both its silence and cover up of adverse information which should result in liability" (*id.* at 18). Defendants reply that Plaintiff's principal argument—that § 360k(a) does not apply here because the premarket approval of the Infuse device extends only to certain uses of that device—is contrary to law and to FDA practice (Dkt 53 at 6).

2. *Implied Preemption*

Section 337(a) of the MDA provides that all actions to enforce FDA requirements "shall be by and in the name of the United States." 21 U.S.C. § 337(a). Citing § 337(a), the United States Supreme Court opined that "[t]he FDCA leaves no doubt that it is the Federal Government rather than private litigants who are authorized to file suit for noncompliance with the medical device provisions." *Buckman*, 531 U.S. at 349, n.4. Indeed, the Supreme Court interpreted this provision to mean that even state claims that run parallel to federal requirements are impliedly preempted unless they are grounded in traditional state tort law and do not depend exclusively on a federal requirement. *Id.* at 353.

As pointed out by other courts, this does not mean that a plaintiff can never bring a state law claim based on conduct that violates the FDCA. *Dunbar,* 2014 WL 3056026, at *3. In fact, the

conduct that gives rise to the claim must violate the FDCA to escape express preemption. *Id.* Instead, to avoid implied preemption, the conduct giving rise to the state claim must also be the type of conduct that would traditionally give rise to liability under state law "even if the FDCA had never been enacted." *Id.* (citing *Houston v. Medtronic, Inc.*, 957 F. Supp. 2d 1166, 1175 (C.D. Cal. 2013) (*Houston I*)).

Defendants argue that to the extent that Plaintiff's claims seek to enforce the provisions of federal law purportedly governing the promotion of medical devices for "off-label" uses or a manufacturer's communications with the FDA, these claims are also impliedly preempted under *Buckman* and prohibited by the FDCA's "no private right of action" provision, 21 U.S.C. § 337(a) (Dkt 51 at 21-32). In response, Plaintiff emphasizes that he is not claiming that Defendants committed "some fraud on the FDA," but a "fraud on the end-users of Infuse: surgeons and their patients" (Dkt 52 at 17). Plaintiff argues that his claim is "clearly viable under *Buckman*" and points out that several of the district courts that have addressed Defendants' preemption argument have held that the claims Plaintiff pursues here are not impliedly preempted under *Buckman* (*id.*).

3. *Independent Federal & State Law Grounds*

Last, Defendants argue that in addition to being expressly and impliedly preempted, Plaintiff's claims fail on independent federal and state-law grounds (Dkt 51 at 33-36). Specifically, Defendants argue that Plaintiff's failure to warn and negligence claims must both be dismissed because, pursuant to the learned intermediary doctrine and Michigan's codification of the sophisticated user doctrine, Defendants had no duty to provide Plaintiff's surgeons warnings beyond those required by the FDA through the premarket approval process, to wit: the FDA-approved labeling for the Infuse device (*id.* at 33-34). Defendants also cite multiple reasons why Plaintiff's

breach-of-warranty claim fails: Defendants unambiguously disclaimed all warranties; there is no privity of contract between the parties; and Plaintiff failed to identify any affirmation of fact or promise that was the basis of the sale of the Infuse device (*id.* at 34-35). Last, Defendants argue that Plaintiff has not satisfied the federal pleading requirements regarding his claim that Medtronic failed to submit adverse event reports to the FDA as required by federal law (*id.* at 35).

As Defendants point out in reply (Dkt 53 at 6-7), Plaintiff wholly failed to address in his response to their motion any of Defendants' arguments that his claims fail on independent federal and state-law grounds.

B. Plaintiff's Claims

1. *Failure to Warn*

In Count I ("Failure to Warn"), Plaintiff alleges that (1) Defendants had a "duty to refrain from promoting, either directly or indirectly, the off-label use of Infuse;" (2) Plaintiff and his physician relied on Defendants' representations and omissions during off-label promotion, specifically, Defendants' "failure to warn physicians and the public in general of the dangers of off-label use of Infuse;" and (3) Plaintiff was proximately injured by Defendants' failure to warn about the dangers of off-label use of Infuse "for the reason that he never would have consented to the use of Infuse during his spinal surgery had he known or been told of the risks of harm or that it had not been approved by the FDA for his particular surgery" (Dkt 35, Amend. Compl. ¶¶ 37-39).

The first step of the express preemption analysis, whether the FDA has established requirements applicable to the particular medical device at issue, *Riegel*, 552 U.S. at 321, is automatically satisfied where, as here, the device has received premarket approval (PMA). The second step of the express preemption analysis, the only step at issue here, requires this Court to

determine whether the state requirements upon which Plaintiff's claim is based are "different from, or in addition to," the federal requirements. *See id.* at 321-22. The parties do not dispute that Michigan law requires manufacturers to provide adequate warnings, and, like the parties, the Court assumes for purposes of the motion that Defendants' conduct allegedly violates state law.

Federal law does not expressly define or ban off-label promotion. Courts have held that the FDCA's misbranding provisions and 21 C.F.R. § 814.80 together constitute "the federal requirements" for purposes of *Riegel's* second step. *Arthur v. Medtronic, Inc.*, No. 4:14-CV-52 CEJ, 2014 WL 3894365, at *5 (E.D. Mo. Aug. 11, 2014) (citing *Beavers-Gabriel v. Medtronic, Inc.*, 15 F. Supp. 3d 1021, 1034-35 (D. Hawaii 2014); *Eidson v. Medtronic, Inc.*, 981 F. Supp. 2d 868, 884-85 (N.D. Cal. 2013); and *Houston I*, 957 F. Supp. 2d at 1179). Specifically, the FDCA prohibits "[t]he adulteration or misbranding of any food, drug, [or] device ... in interstate commerce" and "[t]he introduction or delivery for introduction onto interstate commerce of any food, drug, [or] device ... that is adulterated or misbranded." 21 U.S.C. §§ 331(a) and (b). A device is misbranded if its labeling, or advertising, is "false or misleading." § 352(a) (labeling), § 352(q) (advertising). Whether the labeling or advertising is misleading is determined by considering the "representation made or suggested by statement, word, device, or any combination thereof." § 321(n). Last, FDCA regulations restrict a manufacturer's ability to engage in off-label promotion: 21 C.F.R. § 814.80 states that "[a] device may not be manufactured, packaged, stored, labeled, distributed, or *advertised* in a manner that is inconsistent with any conditions to approval specified in the PMA approval order for the device" (emphasis added). Out of this "muddy statutory and regulatory framework," courts have determined that "federal law bars off-label promotion when it is false or misleading." *Schouest v. Medtronic, Inc.*, 13 F. Supp. 3d 692, 702 (S.D. Tex. Mar. 24, 2014).

Defendants argue that the "gravamen" of Plaintiff's failure-to-warn claim is that Defendants should have made "different" or "additional" statements about Infuse, i.e., warnings beyond those specified by the FDA (Dkt 51 at 19). As other courts have determined, a jury finding that Defendants' labeling was inadequate "would be tantamount to a requirement that Medtronic do something 'different from, or in addition to,' what the FDA already approved." *Schouest,* 13 F. Supp. 3d at 703. Specifically, "a jury would have to find either that Defendants were required to include warnings beyond those in the FDA-approved label for the Infuse Device, or that Defendants were obligated to issue post-sale warnings about potential adverse effects of using the Infuse Device in an off-label manner." *Houston I*, 957 F. Supp. 2d at 1177. Under this line of cases, Plaintiff's failure-to-warn claim here would be expressly preempted.

Plaintiff argues that this Court should instead follow *Ramirez v. Medtronic, Inc.*, 961 F. Supp. 2d 977 (D. Ariz. 2013), clarified on denial of reconsideration (Oct. 24, 2013), where the district court held that the FDA's express preemption provision does not apply when a manufacturer engages in off-label promotion (Dkt 52 at 13-16). The Court is not persuaded. In *Ramirez*, the "core" of the plaintiff's claim was that she was injured due to an off-label use of Infuse that resulted from Medtronic's practice of promoting such uses. *Id.* at 990. Citing 21 U.S.C. § 331(a), the district court decided that "when Medtronic allegedly violated federal law by engaging in off-label promotion that damaged the Plaintiff and thereby misbranded the Infuse device, it departed the realm of federal regulation and returned to the area of traditional state law remedies." *Id.* at 990-91 (footnote omitted). Thus, according to *Ramirez*, the plaintiff's claims were not preempted because "[s]ection 360k protects manufacturers who adhere to the federal regulatory program, but it does not

expand federal law into heretofore unregulated areas," which *Ramirez* determined included the area of off-label promotion. *Id.* at 996.

As evidenced by the plethora of supplemental authorities provided by Defendants, the reasoning of the *Ramirez* district court has been rejected by numerous district courts, although no appellate court has yet considered the precise issue. *See, e.g., Arthur*, 2014 WL 3894365, at *5; *Martin v. Medtronic*, No. 2:14-cv-0385, 2014 WL 3635292 (D. Ariz. 2014) (joining the "majority of other courts" that have held that failure-to-warn claims based on off-label promotion of Infuse are expressly preempted) (citing cases therein); *Beavers-Gabriel*, 15 F. Supp. 3d at 1035 ("*Ramirez* has been rejected—for good reason—by numerous courts."); *McCormick v. Medtronic, Inc.*, 101 A.3d 467, 486 (Md. Ct. App. 2014) (indicating that "*Ramirez* has been almost universally rejected").

The reasoning of *Ramirez* has been rejected as inconsistent with the text of § 360(k), which applies if federal requirements are applicable "to the *device*," not merely to specific uses of devices. The premarket approval application presented to the FDA includes "[a]n identification, discussion, and analysis of any other data, information, or report relevant to an evaluation of the safety and effectiveness of the device known to or that should reasonably be known to the applicant from any source, foreign or domestic, including information derived from investigations *other than those proposed in the application* and from commercial marketing experience." 21 C.F.R. § 814.20(b)(8)(*ii*) (emphasis added). "Once the FDA has cleared a device for introduction into the stream of commerce, physicians may use the device in any manner they determine to be best for the patient, regardless of whether the FDA has approved the device for this usage." *Cooper v. Smith & Nephew, Inc.*, 259 F.3d 194, 197 (4th Cir. 2001). "'[O]ff-label' usage of medical devices ... is an

accepted and necessary corollary of the FDA's mission to regulate in this area without directly interfering with the practice of medicine." *Buckman*, 531 U.S. at 350.

A second related reason courts have therefore determined the reasoning in *Ramirez* is not sound is that the *Ramirez* court presumed that the state-law claims before it were premised on off-label promotion that violated the FDCA. *See, e.g., Alton v. Medtronic, Inc.*, 970 F. Supp. 2d 1069, 1096 (D. Or. 2013) ("[T]he reasoning of *Ramirez*, although largely persuasive, ... depend[s] in part on a flawed premise ... in connection with the court's finding that Medtronic violated federal law specifically by promoting off-label applications of the Infuse device.").

Section 331(a), the provision the *Ramirez* court cited in support of the proposition that "[a] manufacturer is ... prohibited from promoting a use of the product that is not the specified use," does not expressly prohibit such promotion; rather, as recounted above, § 331 prohibits manufacturers only from the "introduction or delivery for introduction into interstate commerce of any ... device ... that is ... misbranded," 21 U.S.C. § 1331(a). *Alton*, 970 F. Supp. 2d at 1096. Misbranding is defined in part as labeling a device without including "adequate directions for use," 21 U.S.C. § 352(f)(1), and directions for use "may be inadequate because ... of omission, in whole or in part, or incorrect specification of ... [s]tatements of all conditions, purposes, or uses for which such device is intended," 21 C.F.R. § 801.5(a), and whether a particular use is intended may be inferred from, inter alia, the manufacturer's statements in promotion of the device and its applications, 21 C.F.R. § 801.4. *Id.* Hence, contrary to the conclusion of the *Ramirez* court, "the promotion itself did not violate any provision of the FDCA, but rather constituted evidence material to the question whether the Infuse device was misbranded." *Id.*

In other words, "rather than escaping federal requirements by promoting an off-label use, a device manufacturer's off-label promotion itself is subject to specific MDA provisions." *Arthur*, 2014 WL 3894365, at *5 (quoting *Houston II,* 2014 WL 1364455, at *5). *See also McCormick*, 101 A.3d at 486 (indicating that "*Ramirez* has been almost universally rejected" because "federal law does impose requirements regarding off-label use and promotion of devices"). Therefore, after careful consideration of the parties' arguments and review of the legal authorities, the Court agrees that off-label promotion is governed by federal law, which sets the parameters and occupies the field for deciding whether a representation is false or misleading. Accordingly, Plaintiff's Count I, seeking reimbursement for the injuries he suffered due to the alleged inadequacy of the warnings for an off-label use, is a claim that falls within § 360k protection.

Further, Plaintiff's Count I does not state a parallel state-law claim because there is no state law duty to abstain from off-label promotion. "Off-label promotion itself exists only as a creation of the FDCA scheme." *Hawkins v. Medtronic, Inc.*, No. 1:13-CV-00499 AWI SK, 2014 WL 346622, at *19 (E.D. Cal. Jan. 30, 2014) ("A state law cause of action cannot rest solely on the off-label promotion of INFUSE."); *see also Caplinger v. Medtronic, Inc.*, 921 F. Supp. 2d 1206, 1219-20 (W.D. Okla. 2013) ("even the concept of 'off-label use' is a creature of the FDCA, is defined by the FDCA, and is not a part of Oklahoma substantive law"). "A successful failure-to-warn claim premised on inadequate labeling would therefore disturb the FDA's policy with respect to the regulation of these devices." *Schouest*, 13 F. Supp. 3d at 703-04 (citing *Buckman*, 531 U.S. at 350). Defendants correctly argue that this lack of a traditional state-law duty to refrain from off-label promotion means that Plaintiff's failure-to-warn claim in Count I is also

impliedly preempted. In sum, Count I, in its entirety, is both expressly and impliedly preempted and will be dismissed.

2. *Negligence & Gross Negligence*

In Count II of his Amended Complaint, Plaintiff alleges "Negligence and Gross Negligence" based on Defendants' duties to (a) "[p]rovide truthful information to the FDA when seeking approval of its device," (b) "[m]arket and sell Infuse only for its approved purposes," (c) "[m]arket and sell Infuse only in ways which do not present an unreasonable risk of harm to the end users of the product," and (d) "[c]omply with all direction of the FDA, including the obligation to provide the FDA with updated information, research and testing which could affect the original FDA approval of its device" (Dkt 35, Amend. Compl. ¶ 41). Plaintiff alleges that the product was not reasonably safe for off-label use at the time it left the control of Defendant seller because Defendants intended and did in fact promote the off-label use of Infuse, which use had not been approved by the FDA (*id.* ¶ 42). Plaintiff alleges that Defendants breached their duties by committing or omitting the following acts: (a) "failing to report adverse consequences of its preapproval testing of Infuse," (b) "failing to refrain from promoting off-label use of Infuse," (c) "failing to warn the public of the dangers and risks of off-label use of Infuse," and (d) "failing to report adverse consequences to the FDA as the Defendants became more and more aware of the dangers of off-label use of Infuse" (*id.* ¶ 43). The Court will address each of the four allegations, in turn.

Plaintiff's negligence claim in ¶ 41(a) based on a duty to "[p]rovide truthful information to the FDA when seeking approval of its device," even if not expressly preempted, is impliedly preempted under *Buckman* and prohibited by the "no private right of action" provision of the

FDCA.[2] "[A] state-law claim that the defendant made misrepresentations to the FDA is preempted because such a claim would not exist absent the federal regulatory scheme established by the FDCA." *Caplinger*, 921 F. Supp. 2d at 1214. "If the claim would not exist in the absence of the FDCA, it is impliedly preempted." *Loreto v. Procter & Gamble Co.*, 515 F. App'x 576, 579 (6th Cir. 2013). *See Purchase v. Advanced Bionics, LLC*, 896 F. Supp. 2d 694, 696 (W.D. Tenn. 2011)) ("[E]ven if a claim survives express preemption, it may be impliedly preempted if it amounts to a disguised fraud-on-the-FDA claim.").

Turning next to Plaintiff's negligence in marketing claims in ¶ 41(b) and (c), the Court agrees with Defendants that the "gravamen" of these claims, like Plaintiff's failure-to-warn claim in Count I, is that Medtronic should have made "different" or "additional" statements about Infuse, i.e., warnings beyond those specified by the FDA (Dkt 51 at 19). The Court's prior analysis and conclusion is therefore applicable here, too, and the Court concludes that Plaintiff's negligence claims in ¶ 41(b) and (c) are expressly preempted. *See Scanlon v. Medtronic*, No. 13-224, 2014 WL 3737501, at *6 (D. Del. 2014) (the plaintiff's negligence cause of action is preempted because it would "impose requirements on Medtronic—to perform and report additional studies—which are different from and in addition to those imposed by the FDA"); *Martin*, 2014 WL 3635292, at *14 (same).

Moreover, Plaintiff's negligence claims based solely on illegal off-label promotion are impliedly preempted because any claim that Defendants engaged in illegal off-label marketing of the Infuse device "'exists solely by virtue' of federal regulations, and is not rooted in any traditional

[2]Further, Plaintiff appears to abandon this claim inasmuch as he indicated in response to Defendants' motion that he "does not claim that Defendants (or their predecessors) did anything improper during the actual approval process" (Dkt 52 at 3).

state tort law." *See Houston I*, 957 F. Supp. 2d at 1178 (quoting *Buckman*, 531 U.S. at 353); *see also Blankenship v. Medtronic, Inc.*, 6 F. Supp. 3d 979, 990 (E.D. Mo. 2014) (determining that although Missouri products liability law supported recovery, the conduct the plaintiff alleged relates to Medtronic's promotion of the Infuse device for the off-label uses, "which is a negligence claim that would not exist if the FDCA did not exist").

Last, the Court determines that the negligence claim in ¶ 41(d) based on a duty "to provide the FDA with updated information, research and testing which could affect the original FDA approval of its device" is not expressly preempted because the claim "seeks to hold Medtronic accountable only for failing to do what federal law mandated." *Stengel v. Medtronic*, 704 F.3d 1224, 1234 (9th Cir. 2013) (claims arising from medical pain pump). However, the claim is impliedly pre-empted. Plaintiff points to no adverse event reporting requirements under Michigan law, and the Court agrees that the requirements are administrative requirements of the FDCA. *See Littlebear v. Advanced Bionics, LLC*, 896 F. Supp. 2d 1085, 1092 (N.D. Okla. 2012); *cf. Schouest*, 13 F. Supp. 3d at 706 ("to the extent Schouest can point to a state law duty to report adverse events, and, critically, what FDA reporting regulations Medtronic allegedly violated, this claim could escape preemption"). In sum, Count II, in its entirety, will also be dismissed as preempted.

3. *Breach of Warranty*

Last, in Count III ("Breach of Warranty") of his Amended Complaint, Plaintiff alleges that "[t]hrough its schemes to promote the off-label use of Infuse, Defendants warranted and represented that Infuse was safe for spinal surgeries without causing unreasonable risk of harm" (Dkt 35, Amend. Compl. ¶ 47). Plaintiff bases his "Breach of Warranty" claim on Defendants' "representation and/or statements of express warranty" (*id.* ¶ 48).

The Court agrees with those courts that have found that an adequately pleaded claim for breach of express warranty is not expressly preempted by § 360k(a). Federal law "already requires [Medtronic] to ensure that any warranty statements it voluntarily makes are truthful, accurate, not misleading, and consistent with applicable federal and state law." *Riley*, 625 F. Supp. 2d at 788; 21 U.S.C. § 331(b). *See also Arthur*, 2014 WL 3894365, at *8; *Houston I*, 957 F. Supp. 2d at 1180-81.

An adequately pleaded express-warranty claim also survives implied preemption because Michigan recognizes claims for breach of express warranty. *See infra.* In other words, Plaintiff's theory is not wholly dependent on federal law—his breach of express warranty claim would exist absent the FDCA and MDA. *See, e.g., Arvizu v. Medtronic, Inc.*, No. CV-14-00792, 2014 WL 4204933, at *9 (D. Ariz. Aug. 25, 2014); *Schouest*, 13 F. Supp. 3d at 707 (the plaintiff's "express warranty claim can survive to the extent she seeks to recover based on false warranties that Medtronic voluntarily and falsely made beyond the federally approved warning").

The remaining question is whether Count III is adequately pleaded, and the determinative issue is whether Plaintiff adequately pleaded that Defendants made an express warranty. The Uniform Commercial Code, as adopted by Michigan, defines an express warranty as "[a]n affirmation of fact or promise made by the seller to the buyer which relates to the goods and becomes part of the basis of the bargain creates an express warranty that the goods shall conform to the affirmation or promise." MICH. COMP. LAWS § 440.2313(1)(a). A seller may disclaim implied warranties under Michigan law as long as the disclaimer is conspicuous. *See* MICH. COMP. LAWS § 440.2316(2); *see also* MICH. COMP. LAWS § 440.1201(10) (providing that a term or clause is conspicuous "when it is so written that a reasonable person against whom it is to operate ought to have noticed it").

Here, the FDA label for the Infuse device states that "[n]o warranties, express or implied, are made" and that "[i]mplied warranties of merchantability and fitness for a particular purpose or use are specifically excluded" (Defs.' Ex. 3, Dkt 51-3 at 4). Defendants argue, with no opposition from Plaintiff, that this unambiguous declaration defeats any warranty claim based on alleged statements outside the Infuse device's labeling (Dkt 51 at 34, citing *Bailey Farms, Inc. v. NOR-AM Chem. Co.*, 27 F.3d 188, 193 (6th Cir. 1994) (applying Michigan law and holding that "both the UCC and common law allow defendant to disclaim implied warranties")).

Defendants also argue that there is no privity of contract between the parties, and that Plaintiff failed to identify any affirmation of fact or promise that was the basis of the sale of the Infuse device (Dkt 51 at 34-35). Again, Plaintiff fatally provides no opposition to Defendants' arguments. *See Notredan, L.L.C. v. Old Republic Exch. Facilitator Co.*, 531 F. App'x 567 (6th Cir. 2013) (recognizing that the plaintiff had waived claim by failing to respond to or refute arguments made by the defendants in the district court); *Allstate Ins. Co. v. Global Med. Billing, Inc.*, 520 F. App'x 409, 412 (6th Cir. 2013) (same); *Humphrey v. U.S. Att'y Gen.'s Office*, 279 F. App'x 328, 331 (6th Cir. 2008) (holding that the defendant waived any argument on the issue by failing to oppose a motion to dismiss); *Scott v. Tenn.*, 878 F.2d 382 (6th Cir.1989) (affirming district court's grant of the defendant's unopposed motion to dismiss, and noting that "if a plaintiff fails to respond or to otherwise oppose a defendant's motion, then the district court may deem the plaintiff to have waived opposition to the motion").

Thus, Defendants' motion operates to defeat Plaintiff's Count III, and Count III will also be dismissed. *See, e.g., Martin*, 2014 WL 3635292, at *16 (the plaintiff's express warranty claim is dismissed, "not because it is preempted, but because she has not alleged what specific warranties

were made to her or to her physicians"); *Mendez v. Shah*, No. 13-1585, 2014 WL 2921023, at *8 (D. N.J. 2014) ("Although [the] plaintiff refers to advertising and marketing of Medtronic products off-label, she does not specifically state what Medtronic expressly warranted"); *Schouest*, 13 F. Supp. 3d at 708)"While conceptually an express warranty claim could avoid express preemption, what is missing from Schouest's complaint, in its current form, is a description of what specific warranties Medtronic made to Schouest or her physicians"); *Ramirez*, 961 F. Supp. 2d at 1001 (dismissing breach of express warranty claim because "any affirmation that forms the basis of an express warranty must be between the seller and the buyer" and Ramirez "does not allege (in anything other than the most conclusory manner) that Medtronic targeted her with its guarantees of safety in off-label use of Infuse"); *Houston I*, 957 F. Supp. 2d at 1181 (holding that although the express warranty claim was not federally preempted, the plaintiff had not alleged sufficient facts for the claim to survive dismissal under Rule 8 where the "[p]laintiff alleged no facts demonstrating that Defendants made any affirmations specifically to Plaintiff or her physician so as to form the basis of the bargain").

IV. CONCLUSION

For the foregoing reasons, the Court determines that Defendants' Motion to Dismiss (Dkt 50) is granted. An Order will be entered consistent with this Opinion. As this Order resolves all pending claims, a corresponding Judgment will also enter. *See* FED. R. CIV. P. 58.

Dated: January 23, 2015

/s/ Janet T. Neff
JANET T. NEFF
United States District Judge